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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,207	08/28/2003	Aaron W. Janke	279.093US3	9733

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EXAMINER
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EVANISKO, GEORGE ROBERT

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 07/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/650,207

Applicant(s)

JANKE ET AL.

Examiner

George R. Evanisko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/3/05</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/3/05 has been entered.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9, 10, and 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Altman (5551427). Altman shows in figures 8 and 9 the use of an insulative drug on a helix and movement of the helix along the radial axis. In addition, Altman discusses in columns 11 and 15 how the electrodes are used for mapping and therefore his system is “coupleable” to a pulse generator.

Claims 9 and 11-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Dutcher et al (5217028). Dutcher discloses the use of mesh, 146 or 152, helix, 131, and the claimed “insulative material on at least a portion” of the fixation device’s surface as plastic/rubber/glass plug, 138, loaded with steroids (column 4) or other drugs (incorporated by reference).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 and 7-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bisping (4886074).

Bisping discloses the claimed invention in figures 1-5 with electrode, 3, guiding mechanism, 8, movement assembly, 5, 9, and 3, with piston, 5, base, 3, knob, 9 or 12, slot, 10 or 11a, and helix, 7, except for the mesh screen disposed on the electrode tip and the helix having an insulating coating with an active ingredient, such as an anti-inflammatant. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the heart lead as taught by Bisping, with a mesh screen disposed on the electrode tip and the helix having an insulating coating with an active ingredient, such as an anti-inflammatant since it was known in the art that heart leads use a mesh screen disposed on the electrode tip to allow fibrous

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connective tissue to intertwine with the screen to firmly secure the electrode and since it was known in the art for heart leads to use a helix having an insulating coating with an active ingredient, such as an anti-inflammatant, to allow the electrical properties (impedance, current density, etc) of the helix to be changed for more effective sensing and pacing and to include an active ingredient in the insulation to reduce irritability and inflammation of the helix.

Claims 1, 2, 3, and 7-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grassi (4624265).

Grassi discloses the claimed invention in figure 4 with electrode, 21, guiding mechanism, 20, movement assembly, 14 and 17, seal, 16, base, 17, and piston, 14 between seals 16, and helix, 15, except for the mesh screen disposed on the electrode tip and the helix having an insulating coating with an active ingredient, such as an anti-inflammatant. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the heart lead as taught by Grassi, with a mesh screen disposed on the electrode tip and the helix having an insulating coating with an active ingredient, such as an anti-inflammatant since it was known in the art that heart leads use a mesh screen disposed on the electrode tip to allow fibrous connective tissue to intertwine with the screen to firmly secure the electrode and since it was known in the art for heart leads to use a helix having an insulating coating with an active ingredient, such as an anti-inflammatant, to allow the electrical properties (impedance, current density, etc) of the helix to be changed for more effective sensing or pacing and to include an active ingredient in the insulation to reduce irritability and inflammation of the helix.

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grassi.

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Grassi discloses the claimed invention except for the knob and slot mating with the knob to form a stop mechanism. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the heart lead as taught by Grassi, with a knob and slot mating with the knob to form a stop mechanism since it was known in the art that heart leads use a knob and slot mating with the knob to form a stop mechanism to prevent the helix from being retracted further into the lead and causing damage to the lead.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bisping or Grassi as applied to claim 1 above. The modified Bisping or Grassi discloses the claimed invention with a traveling helix through a mesh screen except for the groove guide. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the mesh and helical lead as taught by the modified Bisping or Grassi, with a groove guide since it was known in the art that leads with traveling helixes use a groove guide to guide the helix through the distal end of the lead body/mesh to smoothly guide the helix to exit and enter the lead body.

### ***Response to Arguments***

Applicant's arguments filed 6/3/05 have been fully considered but they are not persuasive. The arguments that the examiner is using his personal knowledge and that an affidavit should be provided or that references should be provided for the single reference rejections are not persuasive since the examiner has provided numerous references with the previous actions and the applicant has provided numerous references in the IDSs that show all the elements used in the 103 rejections are well known in the art. Some of these references include: Dutcher, '028, helix, mesh, drug insulative coating on helix; Pohndorf et al, '178, drug

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coating on a helix; Struble, '531, insulation on a helix; Altman, '427, drug insulative coating on helix; Heil, '661, mesh screen, drug, and helix; Hoffmann et al, '329, drug insulative coating on fixation device; Ocel, '006, knob and slot; Jammet, '534, knob and slot; Vachon, '780, groove guide; and Bisping, '074, groove guide. In addition, the examiner has provided proper motivation for each of the combinations. This motivation can be seen in the last sentence of the 103 rejections, such as "to allow the electrical properties (impedance, current density, etc) of the helix to be changed for more effective sensing or pacing and to include an active ingredient in the insulation to reduce irritability and inflammation of the helix".

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GRE  
July 15, 2005

GEORGE R. EVANISKO  
PRIMARY EXAMINER

7/15/05